UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

UNITED STATES OF AMERICA ; THE STATES OF CALIFORNIA, DELAWARE, FLORIDA, GEORGIA, ILLINOIS, INDIANA, HAWAII, LOUISIANA, MASSACHUSETTS, MICHIGAN, MONTANA, NEW HAMPSHIRE, NEW MEXICO, NEW YORK, NEVADA, TENNESSEE, TEXAS, VIRGINIA, NEW JERSEY, CITY OF NEW YORK, CITY OF CHICAGO AND THE DISTRICT OF COLUMBIA *ex rel.* RONALD RAINERO,

Relator-Plaintiff

v.

PFIZER INC.,

Defendant.

FILED IN CAMERA & UNDER SEAL

JURY TRIAL DEMANDED

CIVIL ACTION NO. 07-CA-11728 (RCS) DPW

COMPLAINT FOR VIOLATIONS OF THE FEDERAL FALSE CLAIMS ACT [31 U.S.C. §3729 *et seq.*]; CALIFORNIA FALSE CLAIMS ACT [Cal. Gov. Code §12650 *et seq.*]; DELAWARE FALSE CLAIMS & REPORTING ACT [6 Del. C. §1201 *et seq.*]; DISTRICT OF COLUMBIA PROCUREMENT REFORM AMENDMENT ACT [D.C. Code Ann. §1-1188.14 *et seq.*]; FLORIDA FALSE CLAIMS ACT [Fla. Stat. Ann. §68.081 *et seq.*]; ILLINOIS WHISTLE BLOWER REWARD & PROTECTION ACT [740 ILCS § 175 *et seq.*]; HAWAII FALSE CLAIMS ACT [Haw. Rev Stat § 661-21(a)(3)] MONTANA FALSE CLAIMS ACT; [Mont. Code Ann. §17-/-410, Mont. Code Ann § 17-8-403]; INDIANA FALSE CLAIMS ACT AND WHISTLEBLOWERS PROTECTION ACT [Ind. Code Ann. §5-11-5.5-1-5-11-5.5-18]; MICHIGAN MEDICAID FALSE CLAIMS ACT [Mich. Comp Laws § 400.603,606 and 607]; NEW HAMPSHIRE FALSE CLAIMS ACT [New Hamp. Stat. 167:61-b]; LOUISIANA FALSE CLAIMS ACT [La. Rev. Stat. Ann. § 46:439.1 *et seq.*]; MASSACHUSETTS FALSE CLAIMS ACT [Massachusetts Gen. Laws c.12 §5(A)]; NEW MEXICO MEDICAID FALSE CLAIMS ACT [N.M. Stat. Ann. § 27-14-1-27-14-15]; NEVADA FALSE CLAIMS ACT [Nev. Rev. Stat. Ann. §357.010 *et seq.*]; TENNESSEE MEDICAID FALSE CLAIMS ACT [Tenn. Code Ann. §71-5-181 *et seq.*]; TEXAS MEDICAID FRAUD PREVENTION ACT [Tex. Human Res. Code, Ch. 36, §36.101 *et seq.*]; VIRGINIA FRAUD AGAINST TAXPAYERS ACT [Va. Stat. Ch. 842, Art. 19.1, §8.01-216.1 *et seq.*]; GEORGIA STATE MEDICAID ACT [Ga. Code 49-4-168 *et seq.*]; NEW YORK FALSE CLAIMS ACT [N.Y. St. Finance Law §187 *et* seq.]; NEW YORK CITY FALSE CLAIMS ACT [New York City Administrative Code §7-801-§7-810]; CHICAGO FALSE CLAIMS ACT [Municipal Code of Chicago §1-22-010-§1-22-060]; NEW JERSEY FALSE CLAIMS ACT [N.J. STAT. § 2A:32C-1-17];

THIRD AMENDED COMPLAINT

Relator-Plaintiff Ronald Rainero ("Relator-Plaintiff"), through his undersigned attorneys, on behalf of the United States of America ("United States"), and the State of California, the State of Delaware, the State of Florida, the State of Georgia, the State of Illinois, the State of Hawaii, the State of Indiana, the State of Louisiana, the Commonwealth of Massachusetts, the State of Michigan, the State of New Mexico, the State of Montana, the State of New Hampshire, the State of New York, the State of Nevada, the State of Tennessee, the State of Texas, and the Commonwealth of Virginia, the State of New Jersey, the City of New York, the City of Chicago, in addition to the District of Columbia (collectively, "the States and Cities"), for his Complaint against Defendant Pfizer Inc., alleges as follows:

I. INTRODUCTION

1. This is an action, by and through Relator-Plaintiff Ronald Rainero, to recover treble damages and civil penalties on behalf of the United States and the States and Cities arising from false and/or fraudulent records, statements and claims made, used and/or caused to be made, used or presented by Defendant and/or its agents, and employees in violation of the federal False Claims Act, 31 U.S.C. § 3729 *et seq*. and the state laws referred to in paragraph 2 of this Complaint.

2. Defendant's acts also constitute violations of the California False Claims Act, Cal. Gov. Code §12650 *et seq*.; the Delaware False Claims & Reporting Act, 6 Del. C. §1201 *et seq*.; the District of Columbia Procurement Reform Amendment Act, D.C. Code Ann. §1-1188.14 *et seq*.; the Florida False Claims Act, Fla. Stat. Ann. §68.081 *et seq*.; the Georgia State False Medicaid Claims Act, Ga. Code 49-4-168 *et seq*.; the Illinois Whistle Blower Reward & Protection Act ,740 ILCS § 175 *et seq*.; the Hawaii False Claims Act, Haw Rev. Stat. § 661-21 (a)(3); the State of Indiana False Claims And Whistleblowers Protection Act, Ind. Code Ann. §

5-11-5.5-1-5-11-5.5-18; the Louisiana False Claims Act, La. Rev. Stat. Ann. § 46:439.1 *et seq.*; the Massachusetts False Claims Law, Mass. Gen. Laws ch. 12 §5 *et seq.*; the State of Michigan Medicaid False Claims Act, Mich. Comp Laws § 400.603,606 and 607; the State of Montana False Claims Act, Mont. Code Ann. § 17-8-403,17-8-410; the State of New Mexico Medicaid False Claims Act, N.M. Stat. Ann. § 27-14-1-27-14-15; the New Hampshire False Claims Act, New Hamp. Stat. 167:61-b; the New York False Claims Act, N.Y. St. Finance Law §187 *et seq.*; the Nevada False Claims Act, Nev. Rev. Stat. Ann. §357.010 *et seq.*; the Tennessee Medicaid False Claims Act, Tenn. Code Ann. §71-5-181 *et seq.*; the Texas Medicaid Fraud Prevention Act, Tex. Human Res. Code, Ch. 36, §36.101 *et seq.*; the City of New York False Claims Act, New York City Administrative Code §7-801-§7-810; the City of Chicago False Claims Act, Municipal Code of Chicago §1-22-010-§1-22-060; the New Jersey False Claims Act N.J. STAT. §2A:32C-1-17; and the Virginia Fraud Against Taxpayers Act, Va. Stat. Ch. 842, Art. 19.1, §8.01-216.1 *et seq.* (collectively, the "State False Claims acts").

3. This matter involves illegal marketing practices by Defendant Pfizer Inc., ("Pfizer"), a global pharmaceutical company.

4. On information and belief, since 2001, Defendant Pfizer has been engaged in an illegal marketing scheme for, among other things, the purpose of increasing the sale of its drug Zyvox® (linezolid).

5. Zyvox is an antibiotic that is indicated primarily for use in certain strains of pneumonia and complicated skin and skin structure infections.

6. Relator-Plaintiff Ronald Rainero is a District Manager for Pfizer in the Anti-Infectives Division. He is responsible for the sale of Zyvox in the New York City area. Because of his position, he has unique knowledge of Zyvox's sales and marketing efforts.

7. Pfizer promotes Zyvox for the treatment of catheter related skin infections and concomitant bloodstream infections associated with catheter related skin infections. Zyvox's FDA approved labeling does not support this claim and it constitutes an off-label promotion.

8. Nevertheless, Pfizer promotes Zyvox, both directly and indirectly, for the treatment of catheter related skin infections and concomitant bloodstream infections associated with catheter related skin infections in kidney dialysis centers, chemotherapy/cancer infusion centers and hospitals offering chemotherapy services centers across the United States.

9. Pfizer promotes Zyvox for the treatment of surgical site infections or as a prophylaxis for the prevention of surgical site infections. Zyvox's FDA approved labeling does not support this claim and it constitutes an off-label promotion.

10. Nevertheless, Pfizer also promotes Zyvox, both directly and indirectly, to surgeons across the United States for the treatment of surgical site infections. As will be more fully described below, the promotion of Zyvox for the treatment of surgical site infections, and the subsequent use of Zyvox, has almost certainly resulted in a grave public danger to the public.

11. Pfizer promotes Zyvox as clinically superior to vancomycin. Zyvox's FDA approved labeling does not support this claim and it constitutes an off-label promotion.

12. Pfizer promotes Zyvox as effective for all infections caused by methicillin-resistant Staphylococcus aureus ("MRSA") including community acquired MRSA. Zyvox's FDA approved labeling does not support this claim and it constitutes an off-label promotion.

13. Pfizer promotes Zyvox as an appropriate choice "anywhere on the treatment continuum" regardless of the infection. Zyvox's FDA approved labeling does not support this claim and it constitutes an off-label promotion.

14. Pfizer promotes Zyvox as appropriate empiric therapy for all bacterial infections even though it has no effect on gram negative infections and only partial effect on polymicrobial infections. The promotion of Zyvox as appropriate empiric therapy for all infections constitutes an off-label promotion.

15. Pfizer's irresponsible promotion of Zyvox for non-FDA approved indications such as catheter related infections, soft tissue infections, surgical site infections, all infections caused by MRSA, as empiric therapy and for all bacterial infections "anywhere on the treatment continuum" pose a grave risk to public health because it increases the risk of the development of linezolid resistant eterococcci and bacterial infections that are resistant to Zyvox.

16. Pfizer's illegal promotion of Zyvox as clinically superior to vancomycin also poses a significant public health risk because it illicitly increases Zyvox usage and, in doing so, increases the risk of the development of linezolid resistant eterococcci and bacterial infections that are resistant to Zyvox.

17. For example, the State of New York's Department of Health recently stated that "overuse and misutilization of Zyvox accelerates the development of resistance to Zyvox and limits Zyvox's overall effectiveness."

18. Relator-Plaintiff Rainero also has extensive knowledge regarding the off-label promotion of Bextra®, another pharmaceutical manufactured and distributed by Pfizer.

19. Bextra, which was removed from the market in April 2005, was only indicated for the treatment of osteoarthritis, rheumatoid arthritis and for the primary treatment of dysmenorrhea. However, Pfizer promoted Bextra for, among other things, post-operative pain, pre-operative pain, dental pain and pre-emptive pain.

20. Finally, Relator-Plaintiff possesses knowledge about Pfizer's "Scientific Ambassador Program." The Scientific Ambassador Program is a non-FDA approved marketing scheme wherein Pfizer scientists are used to promote Pfizer drugs off-label and to enable representatives to gain access to difficult to influence physicians.

21. On May 11, 2004 Pfizer entered into a Corporate Integrity Agreement ("CIA") with the Office of the Inspector General ("OIG") of the United States Department of Health and Human Service to promote compliance by its officers, directors, employees, contractors, agents with the statutes, regulations and written directives of Medicare, Medicaid, and all other federal health care programs (as defined in 42 U.S.C. § 1320a-7b(f)) (federal health care program requirements) and the applicable statutes, regulations and written directives of the Food and Drug Administration (FDA requirements).

22. For reasons contained herein, Pfizer's promotional efforts behind Zyvox and Bextra and its "Scientific Ambassador Program" are in violation of this CIA and constitute false claims under the Federal False Claims Act, 31, U.S.C. 3729 *et seq.* and the State and City False Claims acts referenced herein.

II. PARTIES

23. The United States of America, and the above named States and Cities, are the plaintiffs for whom recovery is sought for false and fraudulent claims submitted to Medicaid and other government-funded health programs, including Champus/TriCare and Veteran's Administration funded programs, as well as those of the respective State and City plaintiffs.

24. Relator-Plaintiff Ronald Rainero is a District Manager for Pfizer and is a citizen and resident of the State of New York. He brings this action on his own behalf and on behalf of

the United States pursuant to 31 U.S.C. § 3730(b)(1) and the respective State whistleblower statutes cited in paragraph 2 of this Complaint.

25. Relator-Plaintiff has worked for Pfizer and/or its predecessors for more than 20 years. As a District Manager for Pfizer, Relator-Plaintiff has had 10 or more sales representatives working for him at all times during this period

26. Relator-Plaintiff Rainero possesses a Master of Science in Bacteriology and Public Health from Wagner College in Staten Island, New York.

27. Defendant Pfizer Inc. is a Delaware corporation with its principal place of business in New York, New York. Pfizer is primarily engaged in the manufacture and sale of pharmaceuticals. Pfizer boasts that it is the world's largest research-based biomedical and pharmaceutical company.

28. Defendant Pfizer sells its pharmaceutical products throughout the United States, including in the District of Massachusetts.

29. In 2004, Pfizer entered into a settlement agreement with the Department of Justice, whereby it agreed to pay more than $430 million to resolve criminal charges and civil liabilities related to the promotion of the drug Neurontin (gabapentin) for unapproved, i.e., off-label, uses by the Parke-Davis division of Warner-Lambert, which Pfizer acquired in 2000.

30. As part of this settlement, Pfizer entered into the Corporate Integrity Agreement described above.

31. Similarly, earlier this year, Pfizer agreed to pay $34.7 million to end an investigation by the Department of Justice into the off-label marketing of its human-growth hormone brand, Genotropin, and allegations that a unit of the company made kickbacks to "an outside vendor" in order to increase its sales.

III. FACTUAL ALLEGATIONS

32. Zyvox is an antibiotic that is indicated for use in Nosocomial pneumonia caused by *Staphylococcus aureus* (methicillin-susceptible and -resistant strains) or *Streptococcus pneumoniae* (including multidrug-resistant strains [MDRSP]) and complicated skin and skin structure infections, including diabetic foot infections, without concomitant osteomyelitis, caused by *Staphylococcus aureus* (methicillinsusceptible and -resistant strains), *Streptococcus pyogenes*, or *Streptococcus agalactiae*. These indications are commonly known as pneumonia and skin infections.

33. Zyvox received FDA approval in April of 2000. It was first marketed in the United States in 2001 and is sold in either tablet form, oral suspension powder or in an inactive medium for intravenous injection

34. Since its introduction, Zyvox has come to be used on a regular basis by millions of individuals worldwide, including at least one million in the United States.

35. Zyvox has generated revenues of approximately $782 million in the United States in 2006.

36. Pfizer has more than 360 sales representatives promoting Zyvox to physicians and pharmacists in the United States.

A. Fraudulent Promotion of Zyvox for Catheter Related Infections

37. From the time Zyvox was introduced to market to the present day, Pfizer has directed its sales force to call on physicians that treat large numbers of patients with catheter related bloodstream infections and concomitant bloodstream infections.

38. For example, since 2001, Pfizer provided financial incentives to its sales force to call on nephrologists in kidney dialysis centers and oncologists in chemotherapy/cancer centers.

39. Because of the nature of the treatment provided at these centers, patients at both kidney dialysis centers and chemotherapy/cancer centers are at a high risk to develop catheter related bloodstream infections and concomitant bloodstream infections.

40. Intravascular catheters are one of the most common causes of bacteremia; and catheter related skin infections affect more than 200,000 patients per year in the United States.

41. In fact, kidney dialysis patients suffer catheter related bacteremia infections at a frequency of 2.5 to 5.5 per 1000 patient days.

42. Pfizer has also directed its Zyvox sales representatives to promote Zyvox to vascular surgeons, who commonly treat catheter related skin infections and concomitant bloodstream infections. Vascular surgeons would have virtually no reason to treat pneumonia and skin infections.

43. Pfizer promoted Zyvox for the treatment of catheter related skin infections and concomitant bloodstream infections because it is extremely profitable for the company. Typically, catheter related skin infections and concomitant bloodstream infections require 14 to 21 days of antibiotic therapy. In contrast, an uncomplicated skin infection requires approximately 3 days of therapy, and the standard of care for a pneumonia patient calls for antibiotic therapy not to exceed 7 days.

44. Relator-Plaintiff, as a District Manager in the New York metropolitan area, has unique knowledge of Pfizer's efforts to promote Zyvox at kidney dialysis centers, chemotherapy/cancer centers and to oncologists at hospitals offering chemotherapy, including such prominent hospitals as Memorial Sloan-Kettering Cancer Center.

45. Since Zyvox is only indicated for pneumonia and skin infections, there is virtually no reason for Pfizer's sales representatives to make sales calls promoting Zyvox upon dialysis

centers, chemotherapy/cancer infusion centers and/or hospitals offering primarily chemotherapy services.

46. Nevertheless, Pfizer has authorized and encouraged the sale of Zyvox to oncologists, vascular surgeons and nephrologists.

47. For example, a recent Pfizer sales meeting that occurred from March 28, 2007 to March 30, 2007 at the Kingsmill Resort & Conference Center in Williamsburg, Virginia, featured a session titled "Selling in Cancer Centers."

48. On March 16, 2007, the FDA issued a safety alert about a clinical study of Zyvox's use in the treatment of seriously ill patients with intravascular catheter related bloodstream infections including those with catheter site infections.

49. The FDA Alert was based on findings from an open-label, randomized drug study which compared Zyvox to vancomycin, oxacillin, or dicloxacillin, three generic antibiotics.

50. In the study, patients treated with linezolid (or Zyvox) had an 8% higher chance of death than did patients treated with any comparator antibiotic.

51. In more detail, this study compared Zyvox to the three other generic antibiotics in patients with bloodstream infections related to catheters. This use of Zyvox is not currently approved by the FDA, and therefore would be considered an "off-label" use of Zyvox.

52. The FDA Alert further affirmed that linezolid is not approved for the treatment of catheter related bloodstream infections, catheter-site infections, or for the treatment of infections caused by Gram negative bacteria.

53. Despite this FDA Alert, Pfizer continues to financially incentivize its representatives to call on physicians that treat a disproportionately high number of catheter related skin infections and concomitant bloodstream infections. Additionally, these same

physicians do not typically treat patients for the conditions (i.e., pneumonia, skin infections) for which Zyvox is indicated.

54. Pfizer captures the sales of all the drugs in Zyvox's therapeutic area (Cubicin, Tagacil, vancomycin) for each ZIP code and all accounts within each zip code in the United States. Pfizer sales representatives receive sales bonuses based upon how the market share for Zyvox grows in relation to Cubicin, Tagacil and vancomycin.

55. Because vancomycin is the first line choice for catheter related skin infections and concomitant bloodstream infections, Pfizer sales representatives were and are compelled to sell Zyvox for catheter related skin infections and concomitant bloodstream infections.

56. According to a February 2006 review of the use of Zyvox, Cubicin, Tygacil and vancomycin, Zyvox costs more than eight times a comparable dose of vancomycin.

57. Pfizer also failed to train its representatives about the differences between skin infections and catheter related skin infections. Consequently, when Pfizer representatives promoted Zyvox, no differentiation was made between using Zyvox for a skin infection where Zyvox is indicated and a catheter related skin infection.

58. According to a March 16, 2007 *Reuters* article, a Pfizer representative said that the drug company would not seek FDA approval for any use of Zyvox in patients with catheter related infections: "We don't have plans at this point in time to file for this indication," said Dr. Mark Kunkel, head of Pfizer's anti-infective division.

B. Fraudulent Promotion of Zyvox for Surgical Site Infections

59. Post surgical site infections are a major source of illness across the United States. There are approximately 500,000 post-surgical site infections per year.

60. The University of Pennsylvania Medical Center Guidelines for antibiotic use lists combinations of nafcillin, cefazolin, vancomycin, ampicillin, gentamicin and piperacillin as the first line choices for surgical site infections. Each one of these antibiotics is generic.

61. Relator-Plaintiff Rainero estimates that 35% of the all Zyvox usage is for the treatment of surgical site infections.

62. The Zyvox prescribing information mentions the word "surgical" once and it relates to the potential necessity for "surgical intervention" related to Zyvox induced clostridium difficile associated diarrhea.

63. Pfizer has employed numerous medical education efforts behind the promotion of Zyvox for the treatment of surgical site infections. For example, Lena M. Napolitano, M.D., is a surgeon who has been trained by Pfizer to instruct other surgeons how to use Zyvox for the treatment of surgical site infections. Dr. Napolitano has conducted numerous Zyvox training programs for surgeons across the country for this purpose.

64. Dr. Napolitano is a Professor of Surgery at the University of Michigan School of Medicine and the Chief of Surgical Critical Care and Associate Chair for the Department of Surgery.

65. Even though Zyvox is indicated to treat only pneumonia and simple skin/skin structure infections, Pfizer nevertheless directs its Zyvox sales force to call on surgeons at community hospitals and cancer hospitals throughout the United States. Surgeons are rarely the physicians responsible for treating pneumonia, skin infections and skin structure infections.

66. In a recent email distributed throughout the northeast United States sales region, Pfizer management praised a sales representative for "breaking into surgery early" to secure Zyvox sales with surgeons.

67. Furthermore, senior Pfizer sales management and the Pfizer marketing team have directed Pfizer's sales force to promote Zyvox for the treatment of surgical site infections.

C. Fraudulent promotion of Zyvox as clinically superior to vancomycin

68. In Zyvox's prescribing information, Zyvox achieved cure rates of 61% for nosocomial pneumonia caused by *Staphylococcus aureus*, 59% nosocomial pneumonia caused by MRSA and 100% nosocomial pneumonia caused by *Steptococcus pneumoniae*.

69. The comparator drug for this same analysis, vancomycin, achieved cure rates of 61% for nosocomial pneumonia caused by *Staphylococcus aureus*, 70% for nosocomial pneumonia caused by MRSA and 90% for nosocomial pneumonia caused by *Steptococcus pneumoniae*.

70. In a November 2003 study published in the journal *CHEST* authored by Richard Wunderlink concluded that Zyvox was superior to vancomycin in the treatment of MRSA nosocomial pneumonia ("Wunderlink study"). The promotion of this study would be one of the subjects of a later July 2005 FDA warning letter.

71. In the June 2004 edition of CHEST several FDA scientists, led by Dr. John H. Powers, opined that this study was flawed because it was based on a retrospective subgroup that was not randomized. The letter concluded that "the results of the Wunderlink study support the conclusion that the efficacy of linezolid and vancomycin are similar in patients with NP (nosocomial pneumonia)…Trials of MRSA NP may have logistical difficulties, but this does not justify accepting conclusions or basing future guidelines for patient care *on less than optimal data*." (italics added)

72. In July 2004, Pfizer distributed to sales representatives a document titled "Your Response to a Physician Objection to the *CHEST* letters." The document contained a section for objections and responses.

73. The first physician objection listed was "I can't draw clinical conclusions based on a retrospective analysis." The sales representative was instructed to reply:

> "Although this was a retrospective *analysis*, the *study data* themselves were from 2 identical clinical pneumonia trials; these trials were prospective, randomized, and double-blinded. The data sets were analyzed for this retrospective study, and the study's analysis, are therefore solid and scientifically valid. The reason for combining them was to provide a data set large enough for conclusions to be made." (italics in original)

74. The second physician objection listed was "I can't draw conclusions from a subgroup analysis." The sales representative was provided with two alternative responses:

- "Subgroup analyses are frequently used to inform medical decisions and are often used as the basis for FDA approval of new agents and indications."
- "In large studies like those that formed the basis of the Wunderlink et al analysis, it is very possible that a subgroup could show statistically significant differences while the overall results are similar. This is because the difference in small subgroups can be overwhelmed by the overall population in the full analysis. Furthermore, important conclusions can be drawn from subgroup analyses as shown by Wunderlink et al data: ***ZYVOX demonstrated greater clinical success rates than vancomycin in MRSA nosocomial pneumonia***." (italics added)

75. The document contained additional "Detailing Suggestions" including the following false statement:

- "Always go back to ZYVOX proven efficacy: our data have shown that ZYVOX is better than vancomycin in the treatment of NP (including VAP) due to MRSA."

76. Each of these proposed responses was false, misleading and not supported by Zyvox's FDA approved labeling.

77. Nevertheless, Pfizer engaged in an aggressive promotion of the Wunderlink study and, in April 2005, reported on how successful sales representatives were in communicating the Wunderlink core message.

78. In a document titled "Searle ARM & DM Leadership Briefing - April 25, 2005" Phil Mehl, Director of Division Operations, reported on what doctors recalled about their discussions with Zyvox representatives. Under the section "Zyvox SOV Update: Great news!" Mehl reported that:

- 73% of the doctors reported that representatives told them that Zyvox **was efficacious against MRSA**;
- 50% of the doctors reported that representatives told them that **Zyvox was superior to vancomycin in nosocomial pneumonia**; and
- 23% of doctors reported that representatives told them that Zyvox **was superior to vancomycin in the treatment of complicated skin and skin structure infections**. (italics added)

79. Consequently, sales representatives successfully delivered these off-label messages to doctors nationwide at the direction of senior management at Pfizer.

80. The promotion of Zyvox as "efficacious against MRSA" is an off-label promotion because Zyvox only has indications for the treatment of nosocomial pneumonia caused by MRSA and skin and skin structure infections caused by MRSA. The promotion of Zyvox as "efficacious against MRSA" implies that Zyvox is efficacious against all infections caused by MRSA and constitutes an off-label promotion.

81. The promotion of Zyvox as "superior to vancomycin in nosocomial pneumonia" is an off-label promotion because the Zyvox FDA label states that "the cure rates in clinically evaluable patients were 57% for linezolid-treated patients and 60% for vancomycin-treated patients." The cure rate for nosocomial pneumonia isolated MRSA infection is 59% for Zyvox

and 70% for vancomycin. Accordingly, the marketing message that "Zyvox is superior to vancomycin in nosocomial pneumonia" is, in fact, ***false***.

82. The promotion of Zyvox as "superior to vancomycin in the treatment of complicated skin and skin structure infections" is also false and constitutes an off-label promotion. In Zyvox's FDA approved labeling related skin and skin structure infections, Zyvox was studied against Oxacillin/Dicloxacillin. Zyvox was not studied against vancomycin for skin and skin structure infections. Accordingly, any claim that Zyvox is "superior to vancomycin in the treatment of skin and skin structure infections" is not supported by Zyvox's own FDA approved labeling.

83. All of these promotional messages are not supported by Zyvox's prescribing information and constitute off-label promotions.

84. In July 2005, the FDA issued a warning letter to Pfizer concerning an advertisement that implies that "ZYVOX® is superior to vancomycin for the treatment of nosocomial pneumonia caused by methicillin-resistant Staphylococcus aureus (MRSA)."

85. The FDA letter stated that the advertisement "indicated that ZYVOX® is superior to vancomycin in the treatment of MRSA."

86. The FDA found that the advertisement is "misleading because it implies that ZYVOX® is superior to vancomycin for the treatment of nosocomial pneumonia caused by MRSA when this has not been demonstrated by substantial evidence or substantial clinical experience."

87. Despite this FDA warning, Pfizer continues to promote Zyvox as clinically superior to vancomycin.

88. Pfizer extensively promotes a study authored by John Weigelt titled "Linezolid versus Vancomycin in the Treatment of Complicated Skin and Soft Tissue Infections" ("Weigelt study").

89. Pfizer constructed a sales aid, known as the "Weigelt Cost Analysis", whose purpose was to illustrate both the savings Zyvox utilization provided for MRSA skin infections and Zyvox's clinical superiority in treating MRSA skin infections versus vancomycin.

90. The Weigelt study's summary states that Zyvox's clinical efficacy rate for MRSA skin infections is 88.6% and vancomycin's clinical efficacy rate for MRSA skin infections is 66.9%.

91. In Zyvox's prescribing information, Zyvox's efficacy in the treatment of MRSA skin infections was 67%. There was no comparator drug studied against Zyvox for MRSA skin infections.

92. Consequently, the Weigelt study results clearly state that Zyvox is more efficacious than vancomycin in treating MRSA skin infections. Unlike the data found in Zyvox's prescribing information, this data was not vetted by the FDA.

93. Furthermore, the Weigelt's study results indicate that Zyvox is more effective in treating MRSA skin infections (88.6%) than the MRSA skin infection data present in Zyvox's prescribing information (67%). This finding has not been found to be demonstrated by substantial evidence or substantial clinical experience.

94. Pfizer's widespread promotion of the Weigelt study is evidence that Pfizer disregarded the FDA's July 2005 warnings regarding promotion of Zyvox as clinically superior to vancomycin.

95. Pfizer's Zyvox sales aids also include information communicating that Zyvox is clinically superior to vancomycin in the treatment of MRSA ventilator assisted pneumonia, MRSA nosocomial pneumonia and complicated skin and skin structure infections. Pfizer's dissemination of information that Zyvox is clinically superior to vancomycin in the treatment of MRSA ventilator assisted pneumonia, MRSA nosocomial pneumonia and complicated skin and skin structure infections constitutes off-label promotion.

96. The illicit promotion of the Weigelt study has led to increased usage of Zyvox for MRSA skin infections instead of the equally efficacious and cheaper vancomycin.

97. The illicit promotion of information that Zyvox is clinically superior to vancomycin in the treatment of MRSA ventilator assisted pneumonia, MRSA nosocomial pneumonia and complicated skin and skin structure infections has led to increased usage of Zyovx for these infections instead of the equally efficacious and cheaper vancomycin.

D. Promotion of Zyvox as efficacious for all infections caused by MRSA is an off-label promotion

98. The July 2005 FDA Warning letter also stated that Pfizer's Zyvox advertising implies that "ZYVOX® is approved for the treatment of all infections caused by MRSA."

99. Pfizer's internal documents and sales aids continue to make the claim that Zyvox is effective against all infections caused by MRSA including community acquired MRSA (CA-MRSA).

100. Zyvox's has indications for MRSA nosocomial pneumonia and MRSA complicated skin and skin structure infections.

101. Pfizer Zyvox sales aid states that "CA-MRSA is characteristically and genetically distinct from nosocomial MRSA."

102. Zyvox's FDA approved labeling does not contain an indication for CA-MRSA.

103. Nevertheless, Zyvox is promoted for CA-MRSA infections.

104. The Zyvox sales aid states that "Guidelines support ZYVOX for suspected CA-MRSA infections."

105. In support of this claim, the sales aid states that the "Infectious Diseases Society of America (IDSA) skin and soft tissue guidelines ***suggest*** that when patients present to the hospital with an S *aeureus* infection, the clinician should assume the organism is resistant, because of the high prevalence of CA-MRSA strains. Agents effective against MRSA, including ZYVOX, should be used." (italics added)

106. Consequently, Pfizer is promoting Zyvox for CA-MRSA on the basis of an IDSA ***suggestion*** and not any FDA approved indication. This promotion of Zyvox for CA-MRSA constitutes an off-label promotion.

107. In an internal Pfizer document titled "Zyvox empiric treatment – The Way to $576 million", sales representatives were directed to "reinforce Zyvox as the clear choice for empiric use for MRSA infections." The document failed to clarify what Zyvox's approved MRSA indications were indicating that sales representatives were directed to promote Zyvox for all MRSA infections.

108. In a document titled "Zyvox Mid POA 1 2007", sales representatives were told that "ZYVOX is the clear choice for treatment of MRSA due to its excellent efficacy, excellent tissue penetration, lack of cross resistance and a demonstrated safety profile." The document failed to clarify what Zyvox's approved MRSA indications were indicating that sales representatives were directed to promote Zyvox for all MRSA infections.

109. Pfizer's claim that Zyvox has a "demonstrated safety profile" is highly questionable. In fact, the July 2005 FDA Warning Letter stated that Zyvox "is associated with increased toxicity relative to vancomycin."

E. Promotion of Zyvox as appropriate empiric therapy and appropriate as anywhere on the treatment continuum constitute off-label promotional efforts

110. Pfizer also directs its sales force to promote Zyvox for presumptive or empiric therapy.

111. Bacterial infections are classified as gram positive, gram negative or polymicrobial (comprised of both gram positive and gram negative bacteria).

112. Zyvox is only efficacious in the treatment of gram positive infections. It has absolutely no effect against gram negative infections and is only partially effective in the treatment of polymicrobial infections.

113. There are drugs that are efficacious against gram positive, gram negative and polymicrobial infections. The quinolone class of antibiotics is efficacious against all three types of infections. Examples of the quinalone class of antibiotics are Levaquin and Avelox.

114. Despite the fact that Zyvox is not efficacious against gram negative and polymicrobial infections, Pfizer nevertheless directs its sales force to promote Zyvox as the "clear choice for Empiric treatment" and to reinforce "Zyvox use anywhere on the treatment continuum."

115. The phrase "anywhere on the treatment continuum" means that Zyvox is promoted anywhere antibiotic treatment is warranted. This message constitutes an off-label promotion.

116. The promotion of Zyvox as appropriate empiric therapy is an off-label promotion because Zyvox does not have the indication to treat gram negative and polymicrobial infections.

F. Other Zyvox Marketing Techniques and Their Effect on The Public Health

117. The Zyvox sales force is directed to promote Zyvox as the antibiotic of choice "Right from the Start" regardless of whether the pending lab result warrants the use of Zyvox.

118. Pfizer's use of the "Right from the Start" message promotes the usage of Zyvox regardless of what type of infection the patient has.

119. Pfizer also promotes Zyvox for "step-down-therapy." "Step-down-therapy" is the phrase used to describe the transition from intravenous antibiotics to oral antibiotics of the same brand. Zyvox is one of several antibiotics that are effective against MRSA that come in both intravenous and oral formulations. A partial list of generic drugs that fit these criteria includes clindamycin, doxycycline and trimethoprim/sulfamethoxazole.

120. John Weigelt, M.D., DVM, a professor at the Medical College of Wisconsin and a Zyvox speaker, summarized Pfizer's marketing message for Zyvox by stating that "the ability to treat MRSA with oral ZYVOX may reduce patients' risk for additional infections and allow them to potentially recover in the comfort of their own home without the need for an IV line – which is especially important in instances where the patient would not otherwise be hospitalized."

121. Dr. Weigelt also stated that "[p]revious studies have demonstrated cost savings associated with oral ZVYOX due to shorter hospital stays." This, however, belies the fact that many patients simply cannot afford oral Zyvox upon discharge from the hospital.

122. Oral Zyvox tablets cost approximately $148 a day. The length of Zyvox oral therapy can be anywhere from 3 days to 21 days. For a patient not covered by insurance, this can mean an out of pocket expense anywhere from $444 to $3,108.

123. Relator-Plaintiff Rainero estimates that 35% of the patients in New York City who are placed on Zyvox for "step-down-therapy" are on Medicaid.

124. Pfizer's promotion of Zyvox for "step down therapy" is flawed and endangers public health because the oral form of Zyvox is extremely expensive and many times insurance companies do not cover the medication. When patients attempt to fill the prescription for oral Zyvox they discover that either they cannot afford it or their insurance company will not pay for it. Consequently, patients often fail to fill their oral Zyvox prescription and the full course of Zyvox therapy is not finished. When a patient does not complete the full course of Zyvox therapy the potential for resistance to Zyvox emerges.

125. On January 19, 2007, the State of New York Department of Health ("NYS Medicaid") issued a letter to all Zyvox prescribers concerning the public health risks posed by overuse and misutilization of Zyvox.

126. The letter informed doctors that "due to *public health concerns and the potential for overuse and misutilization*, NYS Medicaid requires that prescribers obtain prior authorization before prescribing Zyvox (linezolid)." (italics added). "This requirement reinforces that prescribers should carefully consider alternatives before initiating Zyvox therapy in the outpatient setting."

127. The letter continued stating that "…overuse of this agent (Zyvox) will accelerate the *development of resistance and limit its overall effectiveness.*" (italics added).

128. The Department of Health letter concluded that "Zyvox should be used only to treat or prevent infections that are proven or strongly suspected to be caused by susceptible bacteria. Cultures should be done and susceptibility proven prior to prescribing this agent. *Zyvox should be reserved for use against Vancomycin Resistant Enteroccocci (VRE).*" (italics added)

129. Mary Denero, a New York City-based Zyvox sales representative, attended a January 2007 Zyvox marketing meeting at Pfizer headquarters in New York City.

130. Ms. Denero shared the highlights of the meeting with the Zyvox New York City regional sales representatives in an email dated January 27, 2007. That email stated that the "POA 2 (Plan of Action) strategies" for Zyvox were to position "*Zyvox as the clear choice for Empiric treatment*" and "*Reinforce Zyvox use anywhere on the treatment continuum.*" (italics added).

131. Pfizer's irresponsible efforts to promote Zyvox "anywhere on the treatment continuum" have been very successful in private doctor's offices. In fact, in May 2006, more than 26% of all Zyvox prescriptions in the New York City area were written by doctors in their private offices.

132. Relator-Plaintiff knows that physicians who write Zyvox in their private offices typically do not culture and sensitize infections for MRSA or VRE before Zyvox is prescribed. It is assumed that if a patient did test positive for MRSA in a private office, he/she would be hospitalized out of fear of contaminating others with MRSA.

133. Less expensive generic drugs exist that are usually as effective as Zyvox in treating MRSA that come in both an IV and oral formulation. A partial list of these drugs includes clindamycin, doxycycline and trimthroprim-sulfamethoxazole. In light of the cost differential between these drugs and Zyvox, it is much more likely that a patient finishes his/her antibiotic therapy if he/she is put on one of these drugs.

134. Although Pfizer does provide a patient assistance program (known as the "RSVP Program") for Zyvox, only a very small percentage of patients who are put on Zyvox for "step-down-therapy" actually use the program.

135. The widespread off-label promotion of Zyvox by Pfizer for non-FDA approved purposes poses a grave public risk because it increases the risk that linezolid resistant eterococci will develop and also increases the risk that more Zyvox resistant bacterial strains will develop.

136. Zyvox is a monoamine oxidase inhibitor and can interact with both serotonergic, adrenergic drugs and tyramine-containing foods. When Zyvox is used in conjunction with selective serotonin reuptake inhibitors, it can cause a potentially deadly reaction known as serotonin syndrome.

137. When Zyvox therapy has lasted more than two weeks, reversible bone marrow suppression has occurred.

138. An article in the October 17, 2007 edition of the New York Times (the "NYT article") reported that nearly 19,000 people died in 2006 after being infected with "virulent drug resistant bacteria" that had spread through hospitals and nursing homes.

139. The researchers in the study quoted in the NYT article estimated that in 2005 approximately 94,360 patients developed an invasive infection from methicillin-resistant Staphylococcus aureus ("MRSA") in 2005 and that nearly one of every five, or 18,650 of them, died.

140. The NYT article further reported that "MRSA, which was first isolated in the United States in 1968, causes 10 percent to 20 percent of all infections acquired in health care settings, according to the disease control agency. Resistant to a number of front-line antibiotics, it can cause infections of surgical sites, the urinary tract, the bloodstream and lungs. *Treatment often involves the intravenous delivery of other drugs, causing health officials to worry that overuse will breed further resistance.*" (italics added).

141. In the July 2007 edition of "Emerging Infectious Diseases", the Centers for Disease Control published a study titled "Response to Emerging Infection Leading to Outbreak of Linezolid-Resistant Eterococci."

142. The study focused on the development of linezolid resistant eterococci ("LRE") in an urban hospital setting.

143. The study tracked linezolid usage at the hospital and found that it had increased three fold in the three years leading up to the outbreak of LRE.

144. The authors found that exposure to linezolid any time in the preceding 12 months and the increased cumulative days of linezolid use among case-patients contributed to multiple clones of LRE at the hospital.

145. The authors concluded that "tracking or restricting linezolid use (e.g., for treatment of invasive VRE (vancomycin resistant eterococci) or MRSA) might reduce antimicrobial drug pressure and slow down the emergence of LRE, *which is critical because only a limited number of antimicrobial drugs are available to treat drug resistant gram-positive infections.*" (italics added).

146. Pfizer's widespread promotion of Zyvox for non-FDA approved indications is also irresponsible because Pfizer fails to provide physicians with FDA-vetted dosing for the indications.

147. Pfizer's promotion of non-FDA approved usages for Zyvox has led to under dosing of Zyvox and over dosing of Zyvox. Both under dosing and over dosing of Zyvox can accelerate development of resistance to Zyvox and limit its overall effectiveness.

G. Other Zyvox promotional efforts

148. Pfizer directs its sales representatives to promote that Zyvox has a "survival benefit" implying that if a doctor used Zyvox rather than vancomycin the patient was more likely to survive.

149. The Zyvox prescribing information does not indicate anywhere that Zyvox provides a survival benefit as opposed to vancomycin.

150. Consequently, the Pfizer promotion that Zyvox has a "survival benefit" constitutes an off-label promotion.

151. Pfizer directs its sales representatives to promote that Zyvox has an "amputation benefit" implying that if a doctor used Zyvox the patient is less likely to lose a limb.

152. The Zyvox prescribing information does not indicate anywhere that Zyvox provides an "amputation benefit."

153. Consequently, the Pfizer promotion that Zyvox has a "amputation benefit" constitutes an off-label promotion.

H. Fraudulent Promotion of Bextra

154. Bextra is a COX-2 selective non-steroidal anti inflammatory drug that was approved for use in the United States in November 2001.

155. The FDA approved Bextra for use in treating pain associated with arthritis and severe menstrual cramps.

156. Between 2001 and May 2005, when the drug was recalled from the market, Bextra was prescribed to millions of patients who suffer from these types of severe pain.

157. The FDA asked Pfizer to withdraw Bextra from the market on April 7, 2005. The FDA determined that Bextra posed too high a risk of adverse cardiovascular events, as well as potentially fatal skin reactions such as Stevens Johnson Syndrome.

158. Pfizer withdrew Bextra from the market in the United States in April 2005.

159. From 2001 until March 2005, Relator-Plaintiff Rainero was a District Manager in New York City responsible for the promotion of Bextra.

160. At various times during this time period, Relator-Plaintiff had at least ten sales representatives reporting to him.

161. It was common practice at Pfizer for District Managers from across the country to share ways to promote the sale of Bextra. Many District Managers shared sales methods to promote Bextra off-label for pain. This is known as the sharing of "best practices." While Bextra was on the market, Pfizer District Managers met monthly at the Staten Island Hilton to share these "best practices" related to the off-label promotion of Bextra.

162. For example, two Pfizer District Managers familiar to Relator-Plaintiff created sales "protocols" for Bextra that included encouraging doctors to prescribe Bextra for off label use.

163. Relator-Plaintiff is in possession of a training document related to these protocols called the "Roadmap to Getting into the Hospital." This document, which was widely distributed throughout the Northeast region, was in fact a training guide to the illegal marketing of Bextra in hospitals.

164. These "protocols" included specific sales messages and documents that encouraged doctors and dentists to use Bextra for pain.

165. For example, Pfizer managers promoted Bextra by an off-label scheme known as "Pathways to Pain."

166. In the "Pathways to Pain" program, erroneous hospital "protocols" with hospital names and logos were distributed at hospitals in New York City which directed physicians to use Bextra for non-FDA approved purposes including, but not limited to, post-operative pain, pre-operative pain, and pre-emptive pain .

167. Relator-Plaintiff Rainero possesses other knowledge and information that Bextra was promoted for post-operative pain, pre-operative pain, dental pain and pre-emptive pain.

168. Relator-Plaintiff Rainero retained documents and electronic mail messages (the "Bextra documents") pertaining to the off-label promotion of Bextra for pain on his computer pursuant to a litigation hold.

169. Relator-Plaintiff Rainero believes that each of the ten representatives that worked for him, as well as numerous other Pfizer employees, had to turn in their computers to the Pfizer's legal department for inspection pursuant to this litigation hold. However, Relator-Plaintiff Rainero was never asked to turn in his computer. Thus, the hard drive of his laptop was never copied or "imaged."

170. In addition, Relator-Plaintiff Rainero later discovered that these Bextra documents were removed from his computer, presumably by Pfizer.

I. Pfizer's Scientific Ambassador Program

171. The Pfizer Scientific Ambassador Program is ostensibly an educational initiative meant to promote Pfizer as a leading pharmaceutical company and to share information with the scientific community.

172. The program enlists Pfizer scientists, designated as "Scientific Ambassadors", to conduct presentations for doctors and researchers regarding Pfizer's drugs and research efforts.

173. However, the presentations include information about research concerning non-FDA approved drugs as well as off-label uses for drugs currently on the market.

174. Relator-Plaintiff possesses information concerning a Pfizer manager, Michael Dunne, MD, promoting the clinical benefits of Selzentry (maraviroc) eight months before the drug received FDA approval.

175. Dr. Dunne illegally promoted the clinical benefits of Selzentry to an audience of physicians, Pfizer sales representatives and Pfizer sales managers at the Jacobi Nursing Residence Center in New York, New York on January 19, 2007.

176. Relator-Plaintiff believes that the same slides that were used by Dr. Dunne used in this presentation were used by Pfizer sales representatives to prime the market for the launch of Selzentry at least seven months before the drug received its FDA approval.

177. Relator-Plaintiff also possesses information about Dr. Paul Miller, a designated Pfizer Scientific Ambassador, collaborating with the Pfizer sales division to promote Pfizer drugs off-label.

178. Relator-Plaintiff possesses information that the sales force was directed to "work hard to over-utilize" the Scientific Ambassador program in order to help drive sales.

179. Additionally, Relator-Plaintiff possesses information that senior sales management at Pfizer received bonuses predicated on the number of Scientific Ambassador programs implemented in their region.

180. In sum, the Pfizer Scientific Ambassador Program is a non-FDA approved marketing scheme that Pfizer erroneously portrays as an educational program. It is simply a

medium by which Pfizer illegally disseminates information about off-label uses for its marketed drugs and information about Pfizer drugs that are not FDA approved.

J. Defendant Pfizer's Participation In Medicaid Program

181. Medicaid is a public assistance program providing for payment of medical expenses for low-income patients. Funding for Medicaid is shared between the federal government and state governments. Although Medicaid is administered on a state-by –state basis, the state programs adhere to federal regulations. The Medicaid program subsidizes the purchase of more prescription drugs than any other program in the United States.

182. The vast majority of patients receiving kidney dialysis in the United States are on Medicaid.

183. In addition to Medicaid, the federal government reimburses a portion of the prescription drugs under several other health care programs, including but not limited to CHAMPUS/TRICARE, CHAMPVA, and the Federal Health Benefit Program.

184. CHAMPUS/TRICARE, administered by the United States Department of Defense, is a health care program for individuals and dependents affiliated with the armed forces. CHAMPVA, administered by the United States Department of Veteran Affairs, is a health care program for the families of veterans with 100 percent service-connected disability. The Federal Employee Health Benefit Program, administered by the United States Office of Personnel Management, provides health insurance for federal employees, retirees, and survivors.

185. Pfizer receives millions of dollars annually as reimbursement for services and products from Medicaid as well as other federal government programs, including but not limited to, CHAMPUS/TRICARE, CHAMPVA, and the Federal Health Benefit Program.

186. Whether pursuant to provider agreements, claims forms, or other appropriate manner, providers who participate in a federal health care program, including Medicaid, CHAMPUS/TRICARE, CHAMPVA, and the Federal Health Benefit Program, generally must certify that they have complied with the applicable federal rules and regulations. Additionally, each provider that participates in the program must sign a provider agreement with its state. Though there are variations in the agreements among the states, the agreement typically requires the prospective Medicaid provider to agree that it will comply with all Medicaid requirements.

K. The Federal False Claims Act

187. The Federal False Claims Act, 31 U.S.C. §§ 3729-32, prohibits the making of false or fraudulent claims for payment or approval, or causing such false or fraudulent claims to be made to the United States in connection with any program, such as Medicaid, which is funded, in whole or in part, by the United States.

188. In making, and causing to be made, claims for reimbursement under the Medicare and Medicaid programs for Zyvox, Pfizer submitted (and caused to be submitted) false and fraudulent claims in violation of the False Claims Act by promoting Zyvox off-label in the following ways:

- For treatment of catheter related skin infections and concomitant bloodstream infections
- For surgical site infections
- For empiric therapy
- For all infections caused by MRSA
- For use "anywhere on the treatment continuum"
- Promoting Zyvox as clinically superior to vancomycin

189. Although at this time it is not possible to estimate the total losses sustained by the federal and state governments under the Medicaid program, the estimated actual and future losses are substantial because Zyvox costs considerably more than Vancomycin. 600 mg of

Zyvox administered twice a day costs approximately $156, whereas the average cost of Vancomycin is less than $18 per day.

190. Relator-Plaintiff estimates that 15% of all Zyvox sales are for catheter related skin infections and concomitant skin infections. Consequently, more than $117 million of Zyvox was sold for off-label uses in 2006 (15% of $782 million). Projected over Zyvox's product life cycle (beginning in 2001), more than $750 million worth of Zyvox has been sold for catheter related skin infections and concomitant skin infections.

191. Relator-Plaintiff estimates that 35% of all Zyvox sales are for surgical site infections. Consequently, more than $273 million was spent on Zyvox to treat surgical site infections in 2006 alone.

192. In making, and causing to be made, claims for reimbursement under the Medicare and Medicaid programs for Bextra, Pfizer submitted (and caused to be submitted) false and fraudulent claims in violation of the False Claims Act by, promoting Bextra off-label for dental pain, pre-operative pain, post-operative pain, pre-emptive pain, preventive pain and Bextra 20mg for rheumatoid arthritis.

193. Although at this time it is not possible to estimate the total losses sustained by the federal and state governments from Pfizer's illegal activities behind Bextra, the estimated actual and future losses are substantial because Bextra cost considerably more than other drugs that actually were indicated for pain. 10 mg of Bextra cost approximately $3.15 per day (2004 price). In alternative, naprosyn, which is indicated for mild to moderate pain, cost $.25 per day for a 375 mg dose (2004 price).

194. Upon information and belief, Defendant's illegal marketing practices in violation of the False Claims Act are being committed on a nationwide basis. Their illegal marketing

practices have resulted in the submission of false claims to Medicaid, CHAMPUS/TRICARE, CHAMPVA, the Federal Health Benefit Program, and other federal health care programs, including but not limited to, those administered by the State Plaintiffs in this case.

195. Upon information and belief, the Defendant's intentional violations of the False Claims Act related to Zyvox are ongoing.

COUNT I
Violations of False Claims Act
31 U.S.C. § 3729

196. Relator-Plaintiff incorporates by reference and re-alleges all above paragraphs as if fully set forth herein.

197. This Count is brought by Relator-Plaintiff in the name of the United States against the Defendant under the *qui tam* provisions of 31 U.S.C. § 3730 for Defendant's violation of 31 U.S.C. § 3729(a)(1) and (a)(2). In violation of 31 U.S.C. § 3729(a)(1) and (a)(2), Defendant made and caused to be made, the false claims that have been set forth in the Complaint herein.

198. Plaintiff United States, unaware of the falsity of the claims and/or statements which Defendant caused doctors, pharmacists, and other health care providers to make to the United States, and in reliance on the accuracy thereof, paid those doctors, pharmacies and other health care providers for claims that would otherwise not have been allowed.

199. The amounts of the false or fraudulent claims to the United States were material.

200. Plaintiff United States, being unaware of the falsity of the claims and/or statements made by Defendant, and in reliance on the accuracy thereof, paid and may continue to pay Defendant for health care services that otherwise should not have been paid under the Medicaid, CHAMPUS/TRICARE, CHAMPVA, and the Federal Health Benefit Program, and other federal health care programs.

201. The United States and the state Medicaid programs have been damaged by the payment of false or fraudulent claims.

WHEREFORE, Plaintiff demands judgment against defendant Pfizer Inc. as follows:

a. That by reason of the aforementioned violations of the False Claims Act this Court enter judgment in Plaintiff's favor and against Pfizer in an amount equal to three (3) times the amount of damages that the United States has sustained because of Pfizer's actions, plus a civil penalty not less than $5,000 nor more than $10,000 for each violation of 31 U.S.C. § 3729;

b. That Relator, as *Qui Tam* Plaintiff, be awarded the maximum amount allowed pursuant to § 3730(d) of the False Claims Act and/or any other applicable provision of the law;

c. That Relator be awarded all costs and expenses of this action, including attorney's fees and court costs incurred in the prosecution of this suit; and

d. That Plaintiff and Relator have such other and further relief that this Court deems just and proper.

COUNT II
Defendant Pfizer's Violation Of The May 2004 Corporate Integrity Agreement With The United States

202. Relator-Plaintiff incorporates by reference and re-alleges all above paragraphs as if fully set forth herein.

203. Pfizer entered into a Corporate Integrity Agreement ("CIA") with the United States Government wherein Pfizer would comply with all applicable FDA requirements concerning methods for selling, marketing, promoting, advertising, and disseminating information about off-label uses of Pfizer's products. A copy of the CIA is attached hereto as Exhibit A.

204. By virtue of the above-described acts, among others, Defendant Pfizer did knowingly and willfully promote Zyvox as clinically superior to vancomycin. The promotion of Zyvox as clinically superior to vancomycin constitutes an off-label promotion.

205. Pfizer's sales, marketing, promotional and advertising efforts behind Bextra and Zyvox have been and continue to be in violation of the CIA.

206. Pfizer's "Scientific Ambassador Program" is a non-FDA approved and illegal marketing scheme which uses Pfizer scientists, in conjunction with the sales division, to promote Pfizer drugs off-label.

207. The "Scientific Ambassador Program" has also been used to illegally promote drugs before they have received FDA approval.

208. Pfizer is now liable to the United States for penalties pursuant to the CIA.

209. Because of Defendant's wanton disregard of this CIA, it is now subject to debarment.

WHEREFORE, Plaintiff demands judgment against defendant Pfizer Inc. as follows:

a. That by reason of the aforementioned violations of the Corporate Integrity Agreement that this Court enter judgment in Plaintiff's favor and against Pfizer for violation of the terms of said Agreement;

b. That Relator be awarded all costs and expenses of this action, including attorney's fees and court costs incurred in the prosecution of this suit; and

c. That Plaintiff and Relator have such other and further relief that this Court deems just and proper.

COUNT III
California False Claims Act
Cal. Government Code §§ 12650-12655

210. Relator-Plaintiff incorporates by reference and re-alleges all above paragraphs as if fully set forth herein.

211. This is a claim against Pfizer for treble damages and penalties on behalf of the State of California under the California False Claims Act, California Government Code §§ 12650-12655.

212. By virtue of the above-described acts, among others, Defendant Pfizer did knowingly and willfully promote Zyvox as clinically superior to vancomycin. The promotion of Zyvox as clinically superior to vancomycin constitutes an off-label promotion.

213. By virtue of the above-described acts, among others, defendant Pfizer did knowingly and willfully promote Zyvox and Bextra, and perhaps other pharmaceuticals for purposes not approved by the FDA.

214. Defendant Pfizer did knowingly and willfully promote Pfizer drugs through the "Pfizer Scientific Ambassador Program" for purposes not approved by the FDA.

215. By virtue of the above-described unlawful acts, Defendant knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the California State Government to approve and pay such false and fraudulent claims under the Medicaid program.

216. The California State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendant, paid and continues to pay the claims that would not be paid but for Defendant's illegal inducements and/or business practices.

217. By reason of Defendant's conspiracy and unlawful acts, the State of California has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

218. The State of California is entitled to the maximum penalty of $10,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendant.

WHEREFORE, Plaintiff demands judgment against defendant Pfizer Inc. as follows:

a. That by reason of the aforementioned violations of the California False Claims Act that this Court enter judgment in Plaintiff's favor and against Pfizer in an amount equal to not less than two times and not more than three times the amount of damages that California has sustained because of Pfizer's actions, plus a civil penalty of not more than $10,000 for each violation of CAL. GOV. CODE §12651(a)(3);

b. That Relator, as *Qui Tam* Plaintiff, be awarded the maximum amount allowed pursuant to CAL. GOV. CODE §12652(g)(2) and/or any other applicable provision of law;

c. That Relator be awarded all costs and expenses of this action, including attorney's fees and court costs incurred in the prosecution of this suit; and

d. That Plaintiff and Relator have such other and further relief that this Court deems just and proper.

COUNT IV
Delaware False Claims and Reporting Act
6 Del C. §1201(a)(1) and (2)

219. Relator-Plaintiff incorporates by reference and re-alleges all above paragraphs as if fully set forth herein.

220. This is a claim for treble damages and penalties against Pfizer on behalf of the State of Delaware under the Delaware False Claims and Reporting Act, 6 Del C. §1201(a)(1) and (2).